Mechanical Stretch Devices for Joint Stiffness and Contractures

Medicare Advantage Medical Policy #MA-198
Original Effective Date: 04/01/2026
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Applies to all products administered or underwritten by the Health Plan, unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

Blue Advantage does not cover investigational or experimental services, including any drug, device, procedure, or service provided under the investigational arm of a clinical trial or study unless mandated by the Centers for Medicare and Medicaid Services. Coverage is limited to routine services for Category A IDE studies and to devices and related services for Category B IDE studies when not supplied by the trial sponsor. Approved IDE studies are posted on www.cms.gov/medicare/coverage/evidence.

When Services May Be Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Health Plan may consider low-load prolonged-duration stretch (LLPS) (Dynamic Splinting) devices for use on the knee, elbow, and wrist or finger to be **eligible for coverage.****

Examples of LLPS devices include Dynasplint System®‡ (Dynasplint Systems Inc.); Ultraflex (Ultraflex Systems Inc.); LMB Pro-Glide devices (DeRoyal Industries); Advance Dynamic ROM®‡, Saunders®‡, Pronex®‡ (Empi).

Patient Selection Criteria

Coverage eligibility may be considered for low-load prolonged-duration stretch (LLPS) (Dynamic Splinting) devices for use on the knee, elbow, and wrist or finger when **ANY** of the following criteria are met:

- As an adjunct to physical therapy in individuals with documented signs and symptoms of significant motion stiffness/loss in the sub-acute injury or postoperative period (≥ 3 weeks but ≤ 4 months after injury or surgery); **OR**
- In the acute post-operative period for individuals who have a prior documentation of motion stiffness/loss in a joint and are having additional surgery or procedures done to improve motion in that joint; **OR**
- As an alternative to manipulation under anesthesia.

Note:
Covered devices will be initially approved for monthly rental for up to four (4) months.
One-time additional monthly rental for up to four (4) months will be approved only when the following criteria are met and documented in medical records:

- *Persistent significant motion stiffness/loss*
- *Significant improvement after initial use*
- *Compliance with conventional therapy and daily device use.*

When Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

The use of low-load prolonged-duration stretch (LLPS) (Dynamic Splinting) devices when patient selection criteria are not met is considered to be **investigational***, including but not limited to:

- The management of chronic fixed contractures due to joint trauma, fractures, burns, brain and spinal cord injuries, rheumatoid arthritis, plantar fasciitis, multiple sclerosis, muscular dystrophy, cerebral palsy, or other chronic conditions; **OR**
- When conventional methods of treating stiff or contracted joints have not been attempted; **OR**
- If there is no significant improvement after four months of use: **OR**
- If initiated more than four months post-operatively (unless it is to be used as an alternative to manipulation under anesthesia); **OR**
- The use on any other joint not mentioned above.

Based on review of available data, the Health Plan considers static progressive stretch devices, e.g. Joint Active Systems®‡ (JAS) Static Progressive Stretch devices (finger, wrist, elbow, shoulder, knee, ankle), JAS®‡ Pronation/Supination device, Static-Pro®‡ Knee, Stat-A-Dyne®‡, AliMed®‡ Turnbuckle Orthosis, and Mayo Aircast®‡ to be **investigational.***

Based on review of available data, the Health Plan considers patient-actuated serial stretch (PASS) devices, e.g. End Range of Motion Improvement ERMI Knee Extensionator, ERMI Knee/Ankle Flexionator, ERMI Shoulder Flexionator, ERMI MPJ Extensionator, and ERMI Elbow Extensionator to be **investigational.***

Background/Overview

Range of Motion Impairments

Loss of full range of motion occurs in a significant proportion of patients following surgical procedures around a joint, such as total knee arthroplasty or anterior cruciate ligament reconstruction. The most common cause of severe postoperative motion loss is the development of intra-articular or extra-articular arthrofibrosis. Arthrofibrosis, characterized by periarticular fibrosis and bands of scar tissue, is described as a painful loss of end range of motion compared with the normal contralateral side. Loss of knee range of motion can lead to impairments in walking, sitting, rising from a chair, and navigating stairs. In 2010, Stephenson et al estimated that based on the annual rates of total knee arthroplasty and anterior cruciate ligament reconstruction, the number of major knee surgery patients affected by arthrofibrosis in the United States would be at least 85,000

per year, and approximately 21,000 patients each year would be at risk of requiring additional surgery.

Treatment

Treatment of arthrofibrosis may include physical therapy, manipulation under anesthesia, arthroscopic or open lysis of adhesions, or revision surgery. Conservative treatment typically consists of postoperative physical therapy with pressure stretching techniques and home exercises. When rehabilitation has failed, serial casting, static braces, or dynamic splints that provide low-load prolonged stretch may be used. Manipulation under anesthesia is safest and most effective after total knee arthroplasty if performed within the first three postoperative months. Dynamic splints use spring loading or elastic bands to provide low-intensity tension (less than that exerted by a physical therapist) and are designed to be worn over relatively long periods (ie, 6-8 hours or overnight). The efficacy of a stretching regimen to permanently remodel tissue is considered to be a function of the intensity, length of the session, number of sessions per day, and number of days per week that stretching is performed.

This medical policy focuses on patient-controlled mechanical devices that provide either moderate- to high-intensity stretch or static progressive stretch in the home. Patient-controlled stretching devices are used at home to increase range of motion in patients who have impaired functional status due to decreased range of motion. We address 2 types of commercially available devices. Static progressive stretch devices (eg, Joint Active Systems [JAS]), Static-Pro) provide low- to moderate-intensity stretching with a crank or ratchet that progressively increases the stretch within each session, and serial stretch devices (eg, End Range of Motion Improvement [ERMI]) use hydraulics to alternate between periods of higher intensity stretch and relaxation.

Improvement in functional outcomes, such as the ability to perform activities of daily living, is the primary goal of this intervention. Joint range of motion is an intermediate outcome. In 2000, 1 small study by Rowe et al. correlated knee range of motion with functional parameters and concluded that 110° is considered the functional range of motion necessary to allow patients to perform common activities of daily living such as navigating stairs, rising from a low chair or commode, entering or exiting a car, or tying one’s shoes. This threshold of range of motion is therefore used as a measure of treatment success for individual patients. Loss of knee range of motion of more than 15°, which occurs in about 1% to 2% of patients after anterior cruciate ligament reconstruction, has been associated with loss of quadriceps muscle strength and the development of osteoarthritis. According to the knee examination form developed by the International Knee Documentation Committee (2000), an extension deficit of 6° to 10° or a flexion deficit of 16° to 25° when compared with the noninvolved knee is categorized “abnormal,” and an extension deficit of more than 10° or a flexion deficit of more than 25° when compared with the noninvolved knee is categorized “severely abnormal.” Range of motion thresholds in joints other than the knee have been less clearly defined.

Low-load Prolonged-duration Stretch (LLPS) (Dynamic Splinting) Devices
LLPS devices permit resisted active and passive motion (elastic traction) within a limited range. LLPS devices maintain a set level of tension by means of incorporated springs. Most spring loaded dynamic splinting devices are designed to provide a low load, prolonged stretch to joints that have reduced range of motion secondary to immobilization, surgery, contracture, fracture, dislocation, or a number of additional non-traumatic disorders. Most of these devices are adjustable-tension controlled units that provide a continuous dynamic stretch while patients are asleep or at rest. Commonly time of use is continuously for 6 – 12 hours, which can be at night or can be two three-hour sessions during the day for less than four months. The objective of stretch therapy is to improve range of motion without compromising the stability and quality of the connective tissue and joint. Currently, dynamic splinting devices are available for but not limited to the elbow, wrist, knee, ankle, and toes. Examples of LLPS devices include Dynasplint System®‡ (Dynasplint Systems, Inc.); Ultraflex (Ultraflex Systems Inc.); LMB Pro-Glide devices (DeRoyalIndustries); Advance Dynamic ROM®‡, Saunders®‡, Pronex®‡ (Empi).

Static Progressive Stretch Devices
Static progressive stretch devices provide a low- to moderate-intensity force to hold a joint at its end range and gradually increase the stretch. In contrast to the long periods of low-intensity stretch provided by dynamic splinting devices, patient-controlled serial stretch and static progressive stretch devices are designed to be used for 15 to 30 minutes, in up to 8 sessions per day. Static progressive stretch devices are available for the knee, shoulder, ankle, wrist, and for pronation and supination. Individuals are typically instructed to use them for 30 minutes, 3 times a day. During each session, individuals adjust their device by turning a ratchet or turnbuckle to the maximum tolerated position of end-range stretch. Each position is held for several minutes to allow for tissue relaxation to occur, and the device is then advanced to a new position of stretch. It is proposed that the systems unload the joint to reduce joint surface pressures during the stretch. Devices that provide static progressive stretch include JAS®‡ (Joint Active Systems), Static-Pro®‡ (DeRoyal), Stat-A-Dyne®‡ (Ortho-Innovations), AliMed®‡ Turnbuckle Orthosis (AliMed), and Mayo Aircast®‡ (DJO).

Serial Stretch Devices
Serial stretch devices (e.g., ERMI) use hydraulics to alternate between periods of higher intensity stretch and relaxation.

Examples include End Range of Motion Improvement ERMI Knee Extensionator, ERMI Knee/Ankle Flexionator, ERMI Shoulder Flexionator, ERMI MPJ Extensionator, and ERMI Elbow Extensionator.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)
The U.S. Food and Drug Administration (FDA) has determined that devices classified as "Exerciser, Non-Measuring" are considered Class I devices and exempt from 510(k) requirements. This

classification does not require submission of clinical data on efficacy, only notification to the FDA prior to marketing. FDA product code: ION

Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

Low-load Prolonged-duration Stretch (LLPS) (Dynamic Splinting) Devices

Evidence from five randomized controlled trials (RCTs) and two uncontrolled studies suggests that low-load prolonged-duration stretch (LLPS) for finger contractures following surgical extensor injury repair may increase range of motion (ROM) faster than static splinting. However, the treatment benefit is small and the final outcome is similar to that achieved with static splinting. Furthermore, LLPS did not significantly improve hand function and grip strength, indicating that the small short-term gains in ROM may not be clinically meaningful and that LLPS may not improve final outcomes. There was a paucity of studies investigating mechanical stretching devices for other applications, including contracture of the fingers following flexor injury or trauma, the hand, wrist, elbow, shoulder, and the knee. Because there were only one or two studies available for each device type, a systematic analysis of the evidence was not possible. No safety issues associated with mechanical stretching devices were identified in the reviewed studies.

Although there is inadequate data in the published peer reviewed literature to validate the effectiveness of dynamic splinting in improving joint range of motion, this technology is widely used in the Orthopedic and Physical Therapy communities for selected patient populations. On the basis of national community standards, dynamic splinting may be considered eligible for coverage with criteria in the clinical settings outlined under the coverage section of this document.

In a systematic review Khan et. al. (2017) evaluated the evidence regarding the effectiveness of non-pharmacological interventions for improved spasticity outcomes in individuals following neurological insults such as stroke, multiple sclerosis (MS), cerebral palsy (CP); or neurological trauma [such as brain injury [BI], spinal cord injury (SCI)]. Non-pharmacologic interventions used in the treatment of spasticity included physical interventions (stretching, passive movements, dynamic splinting). The findings of this review indicated there was low quality evidence regarding the effectiveness of dynamic splinting in the treatment of spasticity in the elbow related to stroke and use of this splinting in the other neurological conditions. Therefore, the evidence remains unclear regarding the use of LLPS (dynamic splinting) for the treatment of spasticity related to various neurological conditions and additional studies are needed to build the evidence regarding the effectiveness of these devices for this indication which should include comparative RCTs to other mechanical stretching devices such as static progressive devices.

Patient-controlled End Range of Motion Stretching Devices

Patient-controlled stretching devices are used at home to increase range of motion in patients who have impaired functional status due to decreased range of motion. We address 2 types of commercially available devices. Static progressive stretch devices (eg, Joint Active Systems, Static-Pro) provide low- to moderate-intensity stretching with a crank or ratchet that progressively increases the stretch within each session, and serial stretch devices (eg, End Range of Motion Improvement ERMI)) use hydraulics to alternate between periods of higher intensity stretch and relaxation.

For individuals who have functional limitations in range of motion who receive static progressive stretch devices and physical therapy, the evidence includes RCTs, a systematic review, and case series. Relevant outcomes include symptoms, change in disease status, functional outcomes, and quality of life. Four RCTs have evaluated static progressive stretch devices but comparators in each differed (physical therapy, a dynamic splint, and a serial stretch device). The evidence on static progressive stretch devices does not currently support an improvement in pain and function with static progressive stretch compared to alternative treatments. One RCT found greater improvements in range of motion and Western Ontario and McMaster Universities Arthritis Index (WOMAC) scores with serial stretch devices for the knee compared with static progressive stretch devices. Another RCT evaluating static progressive stretch for shoulder adhesive capsulitis found significant differences in shoulder range of motion compared with physical therapy alone at the end of 4 weeks of treatment, with no difference in pain and function. A trial reported results of 34 participants with adhesive capsulitis that compared static progressive stretch to physical therapy alone or the combination of stretch and physical therapy. Although significant improvements with static stretching were found compared with placebo in terms of range of motion, differences between groups were generally similar. A fourth RCT found comparable improvements in most outcomes for the static progressive stretch device compared with dynamic splinting, and a systematic review of case reports and series found similar clinical efficacy for increasing elbow range of motion between static progressive stretch devices and dynamic splints. Dynamic splints are used for 8 to 24 hours per day while static progressive stretch devices require several 30 minute sessions. It is not known whether patient compliance is higher with static progressive stretch devices. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have functional limitations in range of motion who receive serial stretch devices and physical therapy, the evidence includes a RCT and observational studies. Relevant outcomes include symptoms, change in disease status, functional outcomes, and quality of life. The best evidence consists of serial stretching with End Range of Motion Improvement (ERMI) devices used to treat knee range of motion. One small RCT and a larger retrospective comparative study have reported that high-intensity stretching with ERMI devices improved range of motion more than lower intensity stretching devices in patients who were post-injury or surgery. Other available data consist of retrospective case series that have demonstrated improved range of motion in patients whose range had plateaued with physical therapy. The clinical significance of gains in this surrogate outcome measure is unclear. Further high-quality comparative trials are needed to determine whether

these patient-controlled devices improve functional outcomes better than alternative treatments and identify the patient populations that might benefit. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Supplemental Information

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

No guidelines or statements were identified.

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

Ongoing and Unpublished Clinical Trials

A search of ClinicalTrials.gov in January 2026 did not identify any ongoing or unpublished trials that would likely influence this review.

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Policy History

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01/20/2026 Utilization Management Committee review/approval. New policy.
Next Scheduled Review Date: 01/2027

Coding

The five character codes included in the Health Plan Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)‡, copyright 2025 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.

The responsibility for the content of the Health Plan Medical Policy Coverage Guidelines is with the Health Plan and no endorsement by the AMA is intended or should be implied. The AMA disclaims responsibility for any consequences or liability attributable or related to any use, nonuse or interpretation of information contained in the Health Plan Medical Policy Coverage Guidelines. Fee schedules, relative value units, conversion factors and/or related components are not assigned by the AMA, are not part of CPT, and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein. Any use of CPT outside of the Health Plan Medical Policy Coverage Guidelines should refer to the most current Current Procedural Terminology which contains the complete and most current listing of CPT codes and descriptive terms. Applicable FARS/DFARS apply.

Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	No codes
HCPCS	E1800, E1801, E1802, E1803, E1804, E1805, E1806, E1807, E1808, E1810, E1811, E1812, E1813, E1814, E1815, E1816, E1818, E1820, E1821, E1822, E1823, E1825, E1826, E1827, E1828, E1829, E1830, E1831, E1832, E1840, E1841
ICD-10 Diagnosis	All related diagnoses

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
    1. Consultation with technology evaluation center(s);
    2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or

3. Reference to federal regulations.

**Medically Necessary (or "Medical Necessity") - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

A. In accordance with nationally accepted standards of medical practice;
B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, "nationally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

‡ Indicated trademarks are the registered trademarks of their respective owners.

NOTICE: If the Patient's health insurance contract contains language that differs from the Health Plan's Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Health Plan recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

NOTICE: Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.

NOTICE: All codes listed on the Medical Policy require prior authorization. This ensures appropriate utilization and alignment with current clinical guidelines.

NOTICE: If an authorization for an ongoing course of treatment has been provided to a member and the member changes from one health plan to another health plan (e.g., a member moves from carrier A to Blue Advantage), Blue Advantage may honor the previous health plan's authorization for the same service under the same type of in-network benefit for a 90-day transition period. Documentation of the authorization for the ongoing course of treatment from the previous health

plan must be provided to us by the member or their provider and the services provided for the course of treatment must otherwise be a covered service under the Blue Advantage health plan.

Medicare Advantage Members
Established coverage criteria for Medicare Advantage members can be found in Medicare coverage guidelines in statutes, regulations, National Coverage Determinations (NCD)s, and Local Coverage Determinations (LCD)s. To determine if a National or Local Coverage Determination addresses coverage for a specific service, refer to the Medicare Coverage Database at the following link: https://www.cms.gov/medicare-coverage-database/search.aspx. You may wish to review the Guide to the MCD Search here: https://www.cms.gov/medicare-coverage-database/help/mcd-benehelp.aspx.

When coverage criteria are not fully established in applicable Medicare statutes, regulations, NCDs or LCDs, internal coverage criteria may be developed. This policy is to serve as the summary of evidence, a list of resources and an explanation of the rationale that supports the adoption of this internal coverage criteria.

InterQual®
Interqual® is utilized as a source of medical evidence to support medical necessity and level of care decisions. InterQual® criteria are intended to be used in connection with the independent professional medical judgment of a qualified health care provider. InterQual® criteria are clinically based on best practice, clinical data, and medical literature. The criteria are updated continually and released annually. InterQual® criteria are a first-level screening tool to assist in determining if the proposed services are clinically indicated and provided in the appropriate level or whether further evaluation is required. The utilization review staff does the first-level screening. If the criteria are met, the case is approved; if the criteria are not met, the case is referred to the medical director.